K083117

MAY 28 2009

510(k) Summary

This summary information is being submitted in accordance with the requirements of The Safety Medical Devices Act of 1990 (SMDA 1990) and 21 CFR Part 807.92.

Assigned 510(k) Number:

Date of Summary Preparation: October 20, 2008

Manufacturer:
Phadia AB
Rapsgatan 7
SE-751 37 Uppsala, Sweden

510 (k) Contact Person:
Martin Mann
Regulatory Affairs Manager
Phadia US Inc.
4169 Commercial Avenue
Portage, Mi 49002, USA
+1 (-269-492) -1957 (Phone)
+1 (-269-492) -7541 (Fax)
martin.mann@phadia.com

Device Name:
EliA™ RNP70 Immunoassay
EliA™ Scl-70 Immunoassay
EliA™ Jo-1 Immunoassay

Common Name:
Antinuclear antibody immunological test system and Control

Classification

Product Name	Product Code	Class	CFR
EliA™ RNP70	LJM	II	866.5100
EliA™ Scl-70	LJM	II	866.5100
EliA™ Jo-1	LJM	II	866.5100

Substantial Equivalence to

Varelisa U1RNP Antibodies	K993589
Varelisa Scl-70 Antibodies	K944172
Varelisa Jo-1 Antibodies	K944173

Intended Use Statements of the New Devices

1) EliA™ RNP70 is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to RNP70 in human serum and plasma (heparin, EDTA) as an aid in the clinical diagnosis of mixed connective tissue disease (MCTD) and systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings. EliA™ RNP70 uses the EliA IgG method on the instrument ImmunoCAP® 100 and ImmunoCAP® 250.

2) EliA™ Scl-70 is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to Scl-70 in human serum and plasma (heparin, EDTA, citrate) as an aid in the clinical diagnosis of scleroderma (diffuse form) in conjunction with other laboratory and clinical findings. EliA™ Scl-70 uses the EliA IgG method on the instrument ImmunoCAP® 100 and ImmunoCAP® 250.

3) EliA™ Jo-1 is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to Jo-1 in human serum and plasma (heparin, EDTA, citrate) as an aid in the clinical diagnosis of polymyositis / dermatomyositis in conjunction with other laboratory and clinical findings. EliA™ Jo-1 uses the EliA IgG method on the instrument ImmunoCAP® 100 and ImmunoCAP® 250.

Special condition for use statement

The device is for prescription use only.

Special instrument requirements

ImmunoCAP® 100/ImmunoCAP® 250 are fully automated immunoassay analyzers, which include software for evaluation of test results.

General Description of the New Devices

The new devices belong to a fully integrated and automated system for immunodiagnostic testing. It comprises a Fluorescence-Immunoassay test system using EliA single wells as the solid phase and is intended to be performed on the instruments ImmunoCAP 100 and ImmunoCAP 250. The conjugate for the EliA IgG method is mouse anti-human IgG beta-galactosidase, which uses 4-Methylumbelliferyl-ßD-Galactoside as substrate. The total IgG calibration is based on a set of six WHO-standardized IgG Calibrators derived from human serum. They are used to establish an initial calibration curve, which may be used for up to 28 days on additional assays and can be stored by the instrument. Each additional assay includes calibrator (curve) controls that have to recover in defined ranges to ensure that the stored calibration curve is still valid. The Fluorescence-Immunoassay test system includes test-, method specific and general reagents that are packaged as separate units.

Test Principle of the New Devices
The EliA Wells are coated with the following antigens:

Test	Antigen coated to the wells:
EliA RNP70	human recombinant RNP (70 kDa) protein
EliA Scl-70	human recombinant Scl-70 protein
EliA Jo-1	human recombinant Jo-1 protein

If present in the patient's specimen, antibodies to the antigens mentioned above bind to their specific antigen. After washing away non-bound antibodies, enzyme-labeled antibodies against human IgG antibodies (EliA IgG Conjugate) are added to form an antibody-conjugate complex. After incubation, non-bound conjugate is washed away and the bound complex is incubated with a Development Solution. After stopping the reaction, the fluorescence in the reaction mixture is measured. The higher the response value, the more specific IgG is present in the specimen. To evaluate test results, the response for patient samples is compared directly to the response for calibrators.

Device Comparison
The new and the predicate devices both represent non-competitive solid phase ELISAs. Both IVDs are used as an aid in the diagnosis of the following diseases:

Disease	Detection of antibodies to
mixed connective tissue disease (MCTD)	RNP70
systemic lupus erythematosus (SLE)	RNP70
scleroderma (diffuse form)	Scl-70
polymyositis / dermatomyositis	Jo-1

Laboratory equivalence
The comparability of predicate device and new device is supported by a data set including

- **results obtained within a comparison study between new and predicate device**
- **results obtained for clinically defined sera**
- **results obtained for samples from apparently healthy subjects (normal population).**

In summary, all available data support that the new devices are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 28 2009

Phadia US Inc.
c/o Mr. Martin Mann
Regulatory Affairs Manager
4169 Commercial Avenue
Portage, MI 49002

Re: k083117
Trade/Device Name: EliA™ RNP70, ELIA™ Scl-70 and EliA™ Jo-1
Regulation Number: 21 CFR 866.5100
Regulation Name: Antinuclear antibody immunological test system
Regulatory Class: Class II
Product Code: LJM, LKO
Dated: April 03, 2009
Received: April 06, 2009

Dear Mr. Mann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: k083117

Device Name: **EliA™ Jo-1**

Indications For Use:

EliA™ Jo-1 is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to Jo-1 in human serum and plasma (heparin, EDTA, citrate) as an aid in the clinical diagnosis of polymyositis / dermatomyositis in conjunction with other laboratory and clinical findings. EliA™ Jo-1 uses the EliA IgG method on the instrument ImmunoCAP® 100 and ImmunoCAP® 250.

Prescription Use __√___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K083117

Concurrence of CDRH, Office of Device Evaluation (ODE)

INDICATIONS FOR USE

510(k) Number: k083117

Device Name: EliA™ RNP70

Indications For Use:

EliA™ RNP70 is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to RNP70 in human serum and plasma (heparin, EDTA) as an aid in the clinical diagnosis of mixed connective tissue disease (MCTD) and systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings. EliA™ RNP70 uses the EliA IgG method on the instrument ImmunoCAP® 100 and ImmunoCAP® 250.

Prescription Use __√___ **AND/OR Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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INDICATIONS FOR USE

510(k) Number: k083117

Device Name: **EliA™ Scl-70**

Indications For Use:

EliA™ Scl-70 is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to Scl-70 in human serum and plasma (heparin, EDTA, citrate) as an aid in the clinical diagnosis of scleroderma (diffuse form) in conjunction with other laboratory and clinical findings. EliA™ Scl-70 uses the EliA IgG method on the instrument ImmunoCAP® 100 and ImmunoCAP® 250.

Prescription Use __√___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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